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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/835,107 | 04/12/2001 | Christopher R. Tudan | SMAR012 | 4208 |

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| EXAMINER |
|---|
| BUNNER, BRIDGET E |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | 13 |

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/835,107 | TUDAN ET AL. | |
| | Examiner | Art Unit | |
| | Bridget E. Bunner | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to a method of reducing the rate of hematopoietic cell multiplication comprising administering an effective amount of a CXCR4 agonist to the hematopoietic cells, classified in class 435, subclass 4.

II. Claims 17-22, drawn to a method of reducing the susceptibility of hematopoietic cells to a cytotoxic agent comprising administering an effective amount of a CXCR4 agonist to the hematopoietic cells prior to or during exposure of the cells to the cytotoxic agent, classified in class 435, subclass 4.

III. Claims 23-26, drawn to a CXCR4 agonist peptide, classified in class 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

a. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions I and II are different methods because they require different ingredients, process steps, and endpoints. Groups I and II are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of administration of a CXCR4 agonist and a reduction in the rate of hematopoietic cell multiplication, which is not required by the other invention. Invention II requires search and consideration of administration of a CXCR4 agonist, exposure of hematopoietic cells to a cytotoxic agent, and reducing the susceptibility of hematopoietic cells to a cytotoxic agent.

b. Inventions III and I/II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as diagnostic assays or immunoassays.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate search requirements and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Restriction to one of the following inventions is further required under 35 U.S.C. 121:

A. The inventions as they pertain to SEQ ID NO: 1, classification dependent upon the nature of the inventions.

B. The inventions as they pertain to SEQ ID NO: 2, classification dependent upon the nature of the inventions.

C. The inventions as they pertain to SEQ ID NO: 3, classification dependent upon the nature of the inventions.

D. The inventions as they pertain to SEQ ID NO: 4, classification dependent upon the nature of the inventions.

E. The inventions as they pertain to SEQ ID NO: 6, classification dependent upon the nature of the inventions.

F. The inventions as they pertain to SEQ ID NO: 8, classification dependent upon the nature of the inventions.

G. The inventions as they pertain to SEQ ID NO: 9, classification dependent upon the nature of the inventions.

H. The inventions as they pertain to SEQ ID NO: 10, classification dependent upon the nature of the inventions.

I. The inventions as they pertain to SEQ ID NO: 11, classification dependent upon the nature of the inventions.

J. The inventions as they pertain to SEQ ID NO: 13, classification dependent upon the nature of the inventions.

K. The inventions as they pertain to SEQ ID NO: 33, classification dependent upon the nature of the inventions.

L. The inventions as they pertain to SEQ ID NO: 34, classification dependent upon the nature of the inventions.

4. The inventions are distinct, each from the other because of the following reasons:

c. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOS: 1-4, 6, 8-11, 13, and 33-34 is a unique sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

A CXCR4 agonist peptide and method of using the peptide, wherein the peptide comprises:

aa. an N-terminal sequence homologous to an SDF-1 N-terminal sequence

bb. a C-terminal sequence homologous to an SDF-1 C-terminal sequence or to a MIP-1α sequence

cc. a peptide spacer sequence linking the N-terminal sequence to the C-terminal sequence

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

A CXCR4 agonist peptide and method of using the peptide, wherein the peptide further comprises:

dd. an internal cyclic amide bridge formed between a carboxylic acid side chain on a first amino acid residue and an amine side chain on a first amino acid residue and an amine side chain on a second amino acid residue

ee. an internal cyclic disulphide or lactam bond between two amino acids

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

A CXCR4 agonist peptide that is encoded by a nucleic acid that hybridizes under stringent conditions to a portion of a nucleic acid encoding:

ff. SDF-1alpha

gg. SDF-1beta

hh. SDF-1 precursor

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**In order to be fully responsive, Applicant must select one from Groups I-III and one from Groups A-L. Applicant is advised that neither I-III nor A-L are species election requirements; rather, each of I-III and A-L is a restriction requirement.**

**If applicant selects Groups I or III, one species from each of the CXCR4 agonist groups must be chosen to be fully responsive.**

**If Applicant selects Group I, one species from the SDF group must be chosen to be fully responsive.**

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

BEB
Art Unit 1647
May 2, 2003

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600